DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 13, 2015

Covidien
Sona Manickam
Senior Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K150084
Trade/Device Name: Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit connector
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: June 12, 2015
Received: June 15, 2015

Dear Sona Manickam,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150084

Device Name
Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit connector

Indications for Use *(Describe)*
The Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit connector are intended for enteral feeding to deliver enteral nutrition, liquid or medication to patient from an enteral feeding syringe or feeding set designed with a connector for enteral applications.

The device is intended for pediatric patients who require enteral feeding.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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2.0 510(k) Summary

Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit Connector

In accordance with section 513(i) of the SMDA and as defined in 21CFR Part 807.92 this summary is submitted by:

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15 Hampshire Street
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Date Prepared: July 09, 2015

a. Contact Person

Sona Manickam
Senior Regulatory Affairs Specialist
Covidien
Telephone: (508) 261-8147
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b. Name of Medical Device

Common Name: tube, feeding

U.S. FDA Classification Product Code: PIF

U.S. Regulation Description: Gastrointestinal tube and accessories, 21 CFR 876.5980

Proprietary / Trade Name: Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit Small Bore Connector

c. Identification of Legally Marketed Device(s)

Argyle Polyvinyl Chloride (PVC) Feeding Tubes, K820441
Argyle Indwell Polyurethane Feeding Tubes, K820442

d. Device Brief Description

The Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit Connector are sterile, disposable medical devices designed to deliver nutrition to patients who cannot obtain nutrition by mouth, are unable to chew or swallow safely, or need nutritional supplementation. The device is designed with a single lumen Polyvinyl Chloride (PVC) or Polyurethane (PU) tubes with ENFit male small bore connector at proximal end.

e. Device Intended Use

The Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit connector are intended for enteral feeding to deliver enteral nutrition, liquid or medication to patient from an enteral feeding syringe or feeding set designed with a connector for enteral applications.

The device is intended for pediatric patients who require enteral feeding.

f. Product Comparison Summary

The proposed and predicate enteral feeding devices are all intended for pediatric patients who require enteral feeding due to illness which prevents normal chewing and swallowing. These products have the same intended use, the same function, and the same general technological characteristics. The majority of the parts for both the proposed and predicate feeding tubes are made with the same material. The variation of the materials for certain components has been proven biocompatible and effective. The major technological enhancement is the incorporation of new ENFit connector which is compliant to ISO 80369-3, in the proposed Feeding Tubes. A male ENFit connector is offered for the proposed feeding tubes. Other additions to the proposed products include additional Fr sizes in both PVC and Polyurethane feeding tubes and an added length to the Polyurethane feeding tubes. These variations do not alter the intended use of the device, nor impact the safety and effectiveness of the product.

g. Nonclinical testing

- Biocompatibility testing has demonstrated the biological safety of parts of the proposed feeding tubes which directly contact the patient.

- Stability testing evaluated the properties of the proposed Feeding Tubes after accelerated aging in support of the product expiration date.

- Dimensional analysis was conducted for critical dimensions of the proposed Feeding Tubes, in accordance with ISO 80369-3, Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. The testing demonstrates the proposed devices conform to the criteria in Table B.2 of ISO 80963-3.

- Study performed on the proposed Feeding Tubes with ENFit Connector included the tests listed below, in accordance with ISO 80369-3, Small- bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications, using the test methods provided in ISO 80369-20, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods. The testing demonstrates the proposed devices conform to the requirements of ISO 80963-3.

Individual Test Defined in ISO 80369-3	Requirement Defined in ISO80369-3	Test Method Defined in ISO 80369-20
Fluid Leakage	Clause 6.2	Annex C
Stress Cracking	Clause 6.3	Annex E
Resistance to separation from axial load	Clause 6.4	Annex F
Resistance to separation from unscrewing	Clause 6.5	Annex G
Resistance to overriding	Clause 6.6	Annex H
Disconnection by unscrewing	Clause 6.7	Annex I

- Flow testing was conducted and has demonstrated that the proposed feeding tubes are substantially equivalent to the performance of the predicate device.

- Liquid Leakage

- Tensile Strength

- The risk associated with the misconnection of the ENFit connector has been assessed.
    - ENFit Misconnection Data with Failure Modes and Effects Analysis (FMEA)
    - Enteral Connector Misconnection Assessment
    - Enteral Connection Risk Management Report
    - ENFit Misconnection Risk Assessment Report

- Human Factors Validation Study

h. Clinical testing

Clinical evaluations were not relied upon for the determination of substantial equivalence to the predicate device based on the device classification, sufficient safety and functional performance information provided in the submission.

i. Conclusions

This information provided within this pre-market notification demonstrates that the Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit Connector have no difference that would affect the safety or effectiveness of the devices as compared to the predicate devices and demonstrate substantial equivalency.

End of Summary